NON-POROUS COATED PTFE GRAFT

CROSS-REFERENCE TO RELATED PATENT APPLICATIONS

1. "BLOOD VESSEL PATCH", Ser. No. 07/358,785, filed concurrently herewith, naming Berguer et al. as inventors, and assigned to the assignee of the present invention.

2. "LONGITUDINALLY COMPLIANT PTFE GRAFT", Ser. No. 07/358,011, filed concurrently herewith, naming Della Corna et al. as inventors, and assigned to the assignee of the present invention, now issued as U.S. Pat. No. 4,955,899.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to prosthetic vascular grafts for implantation within the vascular system of a patient, and more particularly, to a prosthetic vascular graft made from expanded, porous polytetrafluoroethylene (PTFE) tubing that is fabricated to retain the porous inner cylindrical wall of conventional PTFE vascular grafts, but wherein the outer cylindrical wall of the PTFE tube is rendered non-porous over at least a portion of its length.

2. Description of the Prior Art

The use of implantable prosthetic vascular grafts made of expanded, porous PTFE is well known in the art. Such vascular grafts are often implanted just below the skin to provide blood access for long term hemodialysis. Such PTFE vascular grafts are also used to replace or bypass occluded or damaged natural blood vessels. Such prosthetic vascular grafts, and methods of implanting the same, are generally described in Bennion et al., "Hemodialysis and Vascular Access", *Vascular Surgery*, pp. 625–662, 1983. Methods of forming expanded, porous PTFE tubing are well known in the art. For example, U.S. Pat. No. 4,187,390 issued to Gore discloses one such process which may be used to produce highly porous, expanded PTFE structures.

Expanded, porous PTFE material offers a number of advantages when used as a prosthetic vascular graft. PTFE is highly biocompatible, has excellent mechanical and handling characteristics, does not require preclotting with the patient's blood, heals relatively quickly following implantation, and is thromboresistent. Notwithstanding its many advantages, certain problems may arise with the use of PTFE vascular grafts. For example, PTFE material is not very elastic, and the suture holes formed in the ends of the graft when the graft is sutured to a blood vessel during implantation often leak blood until clotting occurs within the suture holes. Moreover, while porous PTFE vascular grafts are generally impermeable to blood, instances have arisen wherein serous weepage has occurred; serous weepage arises when the watery portion of the blood passes through the wall of the PTFE vascular graft and forms a collection of fluid, known as a seroma, adjacent the outer wall of the vascular graft. Additionally, instances have arisen wherein sutures used to secure the ends of PTFE vascular grafts to blood vessels within the body have torn the wall of the PTFE vascular graft, causing failure thereof.

Conventional PTFE vascular grafts have a porous outer cylindrical wall which facilitates tissue ingrowth into the outer cylindrical wall of the vascular graft, thus helping to heal and stabilize the graft. Nonetheless,

there are instances wherein it is desired to preclude such tissue ingrowth. For example, should it later become necessary to perform a thrombectomy to remove a blood clot within the graft, the wall of the graft must be exposed in order to permit the formation of an incision therein. Exposure of the vascular graft is made more difficult if significant tissue ingrowth has taken place. Similarly, there are instances wherein it is desired to implant a jump graft onto a previously existing vascular graft. Once again, the outer cylindrical wall of the original graft must be exposed in order to implant the jump graft. However, the significant tissue ingrowth fostered by conventional PTFE vascular grafts make such exposure more difficult.

Accordingly, it is an object of the present invention to provide a PTFE vascular graft having a porous inner cylindrical wall and including an outer cylindrical wall, at least a portion of which is rendered non-porous for preventing tissue ingrowth and facilitating later exposure of the vascular graft.

It is another object of the present invention to provide such a PTFE vascular graft which eliminates or minimizes suture hole bleeding when the graft is implanted.

It is still another object of the present invention to provide such a PTFE vascular graft which significantly reduces the incidence of serous weepage.

It is a further object of the present invention to provide such a PTFE vascular graft with increased suture retention strength to avoid tearing of the walls of the graft.

These and other objects of the present invention will become more apparent to those skilled in the art as the description thereof proceeds.

SUMMARY OF THE INVENTION

Briefly described, and in accordance with the preferred embodiments thereof, the present invention relates to a PTFE vascular graft having a porous inner cylindrical wall and having an opposing outer cylindrical wall, wherein at least a portion of the outer cylindrical wall is rendered non-porous through the application of a non-porous elastomeric coating thereto. The vascular graft includes an expanded, porous PTFE tube, and a coating of a non-porous elastomer coated to at least a portion of the outer cylindrical wall of the PTFE tube. The coated portion of the PTFE tube precludes tissue ingrowth into the outer cylindrical wall thereof, minimizes blood leakage through any suture holes formed therein, increases suture retention strength, while reducing the incidence of serous weepage.

Non-porous polyurethane is preferably used to form the non-porous elastomeric coating upon the outer cylindrical wall of the PTFE tube. Other biocompatible elastomers which may be used to form such coating include medical-grade silicone rubber elastomers, segmented polyurethanes, polyurethane-ureas, and silicone-polyurethane copolymers.

PTFE vascular grafts can be formed with the above-described non-porous elastomeric coating applied over the entire length of the underlying PTFE tube. Alternatively, the non-porous elastomeric coating may be applied over the outer cylindrical wall of the PTFE tube only along the first and second opposing end portions of the PTFE tube, and not along the central portion thereof. Such end-coated PTFE vascular grafts provide the aforementioned advantages of minimizing suture